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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages In This Submission: 10

Application Number	09/162,648
Filing Date	September 29, 1998
First Named Inventor	John C. Hiserodt
Art Unit	1632
Examiner Name	Shin-Lin Chen, Ph.D.
Attorney Docket Number	SEQ2

ENCLOSURES *(Check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)** (7 pages)
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please identify below):

Last page marker (1 page)

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Meyer Pharmaceuticals LLC		
Signature			
Printed name	J. Michael Schiff		
Date	March 14, 2005	Reg. No.	40,253

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	J. Michael Schiff	Date	March 14, 2005

PTO/SB/17 (12-04v2)
Approved for use through 07/31/2006. OMB 0851-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2005

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 250

Complete if Known	
Application Number	09/162,648
Filing Date	September 29, 1998
First Named Inventor	John C. Hiserodt
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METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☑ Deposit Account Deposit Account Number: 50-3320 Deposit Account Name: Meyer Pharmaceuticals LLC

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☑ Charge fee(s) indicated below, **except for the filing fee**

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims _____ - 20 or HP = _____ x Fee ($) _____ = Fee Paid ($) _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims _____ - 3 or HP = _____ x Fee ($) _____ = Fee Paid ($) _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims: Fee ($) _____ Fee Paid ($) _____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets _____ - 100 = _____ / 50 = _____ (round up to a whole number) x Fee ($) _____ = Fee Paid ($) _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Fee for Appeal Brief under 41.20(b)(2)	250

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	40,253	Telephone	650-327-0960
Name (Print/Type)	J. Michael Schiff			Date	March 14, 2005

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I hereby certify that this correspondence is being transmitted to the U.S. Patent & Trademark Office in accordance with 37 CFR § 1.6(d) on the date indicated.

Name Date March 14/05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of: John C. Hiserodt	Art Unit: 1632
Serial No.: 09/162,648	Examiner: Shin-Lin Chen, Ph.D.
Filing Date: September 29, 1998	
For: CANCER IMMUNOTHERAPY USING ALLOSTIMULATED CELLS IN A MULTIPLE SEQUENTIAL IMPLANTATION STRATEGY	

APPEAL BRIEF

Board of Patent Appeals and Interferences
P.O. Box 1450
Alexandria VA 22313-1450

Dear Sir:

Applicant hereby appeals to the Board of Patent Appeals and Interferences the decision of the Examiner to reject claim 20 of this application.

This paper is applicant's Appeal Brief, submitted in accordance with 37 CFR § 41.37. A Notice of Appeal was filed in this application on August 13, 2004, setting the deadline for filing an Appeal Brief to October 13, 2004. On March 11, 2005, a Request for a five month extension of time was filed, along with the requisite fee, setting the deadline to March 14, 2005, since March 13 is a Sunday. Accordingly, this Appeal Brief is timely filed.

This paper extends the time in which the Examiner may consider the application. Allowance of all claims in the application is respectfully requested.

Real Party in Interest

The party in interest in these proceedings is Meyer Pharmaceuticals LLC, which owns this invention by virtue of an assignment from the inventor.

Related Appeals and Interferences

None

Status of Claims

Claims 10-11, 20, and 23-32 are pending in this application.

Claims 1-9, 12-19, and 21-22 have been cancelled.

Claims 10-11 and 23-32 have been allowed.

Claim 20 stands rejected.

Rejection of claim 20 is hereby appealed.

Status of Amendments

In an after-final amendment filed August 13, 2004, claims 1-9, 12-19 , and 21-22 were cancelled; claims 10-11, and 31-32 were amended. These amendments have been entered into the file, putting claims 10-11 and 23-32 in condition for allowance.

In an after-final amendment filed March 11, 2005, it was proposed to amend claim 20 from its previously presented form:

> 20. A pharmaceutical composition comprising alloactivated lymphocytes allogeneic to leukocytes in a cancer patient packaged with information for the treatment of the patient according to the method of claim 23.

to the following:

20. A product in which the following components are packaged together:
    - a pharmaceutical composition comprising alloactivated lymphocytes allogeneic to leukocytes in a cancer patient; and
    - written information for the treatment of the patient according to the method of claim 23.

This amendment has not yet been entered.

Summary of Claimed Subject Matter

Claim 20 as previously presented and in the proposed amended form covers a commercial product wherein the following components are packaged together:

- a pharmaceutical composition comprising the essential components of the composition used in the treatment method of claim 23, and
- written information that directs the user in the treatment of a cancer patient using the pharmaceutical composition according to the method of claim 23.

This product is described in the specification as filed in the penultimate paragraph before the Example section. The method of claim 23 is described throughout the summary, detailed description, and working examples.

Grounds of Rejection to be Reviewed on Appeal

According to the Advisory Action dated September 22, 2004, claim 20 stands rejected on two grounds:

- the information for treatment of the patient is written on a label or piece of paper, and it is unclear how the information is administered to the patient so as to provide a therapeutic effect
- the pharmaceutical composition *per se* is still obvious in view of teachings in prior art references regarding the use of such compositions in a different manner.

ARGUMENT

The skilled reader will understand from the plain reading of claim 20 that the written information is not part of the pharmaceutical composition. Rather, it is packaged with the composition so as to inform or instruct the user as to how the composition is to be administered. Thus, the information is not administered to the patient. Instead, it is made available to the person administering the composition (i.e., a licensed clinician) so that they may administer the composition in accordance with the method of claim 23, thereby conferring on the patient the benefits of the novel and inventive treatment methods described in this patent disclose.

It is standard practice that instructions of this kind be packaged with any pharmaceutical composition — in fact, written information is required by the Food and Drug Administration to be co-packaged with any pharmaceutical composition subject to regulatory approval. Someone skilled in the art who is reading this patent disclosure will understand the meaning and the use of both the written information and the pharmaceutical composition as indicated in the claim.

Thus, claim 20 complies with all the patentability requirements of 35 USC § 112. Applicant has proposed to amend the claim as shown above for the convenience of the reader, but the reworded claim does not alter the essence of the invention of claim 20. The claim is allowable with either wording.

Non-obviousness of the product in claim 20 must be determined in view of *all* the features of the product *in its entirety*. The claimed product *as a whole* requires the presence not only of the pharmaceutical composition, but also the written information with which it is packaged. The written information is explicit for the treatment of the patient according to the method of claim 23. Since claim 23 has been found to be patentable, written information for the treatment of a patient according to claim 23 must also be free of the prior art of record. Since the written information is a required component of the product of claim 20, the product *as a whole* must also be free of the prior art.

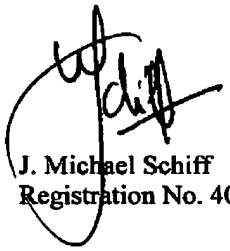
Thus, claim 20 also complies with the patentability requirements of 35 USC §§ 102 and 103.

Applicant respectfully requests that the rejection of claim 20 be withdrawn or reversed, and that the application be allowed *in toto*.

Accompanying this paper is a Fee Transmittal that authorizes the Board to charge the fee for the filing of this Appeal Brief to applicant's deposit account.

Should the Patent Office determine that a further extension of time or other relief is required for further consideration of this application, applicant hereby petitions for such relief and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of this paper to Deposit Account 50-3320.

Respectfully submitted,



J. Michael Schiff
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March 14, 2005

CLAIMS APPENDIX

1 to 9. *CANCELLED*

10. The method of claim 23, further comprising removing any residual tumor at or around the site of the second cell population at a time subsequent to when the second cell population was implanted.

11. The method of claim 23, wherein both the first and second cell populations have one or more of the following features:

i) contain between about 2×10^9 and 2×10^{10} cultured peripheral blood mononuclear cells originating from the donor and between about 1×10^8 and 2×10^9 cultured peripheral blood mononuclear cells originating from the patient or from a second donor;

ii) are obtained by a process in which donor lymphocytes are alloactivated by coculturing ex vivo with stimulator leukocytes for a period of about 48 to 72 hours; or

iii) are obtained by a process in which donor lymphocytes are alloactivated by coculturing ex vivo with stimulator leukocytes and harvested at about the time of initial alloactivation, measurable by acridine orange or CD69 assay.

12 to 19. *CANCELLED*

20. A pharmaceutical composition comprising alloactivated lymphocytes allogeneic to leukocytes in a cancer patient packaged with information for the treatment of the patient according to the method of claim 23.

((

21 to 22. *CANCELLED*

23. An improvement in the method of treating a human patient having a tumor by implanting at or around the site of a solid tumor in the patient a cell population comprising alloactivated lymphocytes that are allogeneic to the patient;

wherein the implanting of the alloactivated lymphocytes results in the patient generating a therapeutic response against tumor growth;

the improvement comprising implanting at or around the site of a solid tumor in the patient a second cell population containing alloactivated lymphocytes that are allogeneic to the patient between 1 and 8 weeks after the implanting of the first cell population.

24. The improved method of claim 23, which elicits an inflammatory response against the tumor.

25. The improved method of claim 23, which elicits an immune response against the tumor.

26. The improved method of claim 23, wherein the alloactivated lymphocytes in at least one of the cell populations are alloactivated against leukocytes of the human patient.,

27. The improved method of claim 23, wherein the alloactivated lymphocytes in at least one of the cell populations are alloactivated against leukocytes of a third-party donor different from the patient or the donor of the lymphocytes.

28. The improved method of claim 23, wherein treatment according to the method has at least one of the following effects in at least 30% of treated subjects:
    a) substantial regression of the tumor in size;
    b) lack of recurrence of a tumor after removal; or
    c) decrease in rate of formation of metastasis.

29. The improved method of claim 23, wherein the tumor is a cancer is selected from melanoma, pancreatic cancer, liver cancer, colon cancer, prostate cancer, and breast cancer.

30. The improved method of claim 23, wherein the first cell population stimulates a response in the patient against the tumor before the implanting of the second cell population.

31. The improved method of claim 23, wherein treatment according to the method causes lack of recurrence of a tumor after removal.

32. The method of claim 23, wherein the first and second cell populations are implanted at or around the site of the same tumor in the patient.

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09/162,648

LAST PAGE